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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,318	10/24/2003	John S. Patton	53207-US-CNT[4]	8226

1095 7590 05/13/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
05/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/693,318
Filing Date: October 24, 2003
Appellant(s): PATTON ET AL.

Guy V. Tucker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/23/2009 appealing from the Office action mailed 6/20/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,522,383	CALVERT et al.	6-1996
4,860,740	KIRK et al.	8-1989
4,396,152	ABPLANALP	8-1983
4,174,712	MOREN et al.	11-1979
4,022,224	SAIFER et al.	5-1977
3,809,084	HANSEN	5-1974

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. (US 5,522,383) in view of Saifer et al. (US 4,022,224).

As to claims 2, 11, 26, and 27, Calvert et al. discloses an apparatus for producing aerosolized medicament, the apparatus comprising: a reservoir (capsule 5a, 5b) containing powder medicament to be aerosolized; and a chamber (25) comprising first and second air inlets (26) and a mouthpiece (27), wherein gas may flow into the chamber through the inlet and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament. Furthermore, Calvert et al. discloses that the gas is introduced to the chamber at a swirl angle to create a vertical flow (col. 4, lines 35-40). To the extent that Calvert et al. does not explicitly disclose that at least 40% by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece, examiner contends that Calvert et al. does explicitly disclose that the device delivers as much of the medicament as possible (col.4, lines 35-55). Depending on the specific characteristics of the powder, the exact percent of medicament delivered would vary to a certain degree, but the structure of Calvert et al. would not prevent at least 40% by weight of the medicament to be suspended and delivered, thereby reading on the instant claim. In addition, to the extent that Calvert et al. is silent as to the volume of medicament aerosolized, absent a critical teaching and/or a showing of unexpected results from the volume of aerosolized medicament being 9.24-21.5% of the volume of the chamber, examiner contends it is an obvious design consideration to one of ordinary skill in the art to aerosolize a large range of medicament volumes, including 9.24-21.5% of the chamber volume, depending on the amount of medicament needed to treat the patient for a given condition and who is using the device (i.e., pediatric, adult). Again, examiner argues that the structure of Calvert et al. does not prevent one of ordinary skill in the art from sizing the chamber such that the volume of aerosolized medicament is 9.24-21.5% of the volume of the

chamber, and it appears as though the device of Calvert et al. would perform equally well with the claimed dimensions. The difference between Calvert et al. and claim 2 is the powder medicament comprising a protein or polypeptide. Saifer et al. teach a protein (e.g. orgotein) in the form of a powder medicament for administration to a patient suffering from smoke inhalation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the powdered medicament of Calvert et al. with a protein such as orgotein as taught by Saifer et al. because it would have provided a means for treating patients suffering from smoke inhalation using the device disclosed by Calvert et al.

As to claims 5, 14, and 30, the chamber disclosed by Calvert et al. is adapted to contain aerosolized medicament for subsequent delivery to a patient (abstract).

As to claims 6 and 15, the chamber (25) of Calvert et al. is cylindrical (Figure 8).

As to claims 7, 16, and 31, although Calvert et al. is silent as to the particle size, it would have been an obvious design consideration to one of ordinary skill in the art to use particles being sized to be deliverable to the alveolar regions of the lungs in order to treat various conditions of the patient by enabling deeper penetration into the respiratory tract of a patient.

As to claims 9, 10, 18, 19, and 33, Calvert et al. as discussed above with respect to claim 2, discloses a need for as high as possible degree of emptying of the reservoir (5a, 5b) and chamber for properly treating a patient (column 4, lines 45-55). Therefore, at least 55% and at least 70% by weight of the powdered medicament being suspended by the gas in the chamber for delivery through the mouthpiece is an obvious design consideration to one of ordinary skill in the art for delivery of as close to a full dose as possible. Furthermore, as discussed above, the structure of Calvert et al. does not prevent this amount of medicament from being aerosolized.

As to claims 20, 23, and 34, Calvert et al. discloses at least one air inlet oriented tangentially in the chamber (Figure 7).

Claims 3, 12, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Moren et al. ('712). While Calvert et al. is silent as to the dimensions of the chamber, the chamber size can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular chamber size including 100ml to 750ml. The treatment of adult patients vs. children would require a larger chamber due to increased tidal volume and lung capacity of adults. Otherwise, resort is had to Moren, which teaches an expansion chamber having a volume in the range of 500ml to 2000ml (see figure) for reducing propellant and generating smaller medicament particles which will more readily follow the path of inhalation (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the chamber of Calvert et al. to have a volume in the claimed range because it would have provided a means for reducing propellant and generating smaller medicament particles which will more readily follow the path of inhalation as taught by Moren. In addition, it appears as though the device disclosed by Calvert et al. would perform equally well with the claimed dimensions.

Claims 4, 8, 13, 17, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Hansen (US 3,809,084).

As to claims 4, 13, and 29 Calvert et al. does not disclose a source of compressed gas for aerosolizing the medicament. However, Hansen, in a powdered medicament inhaler, discloses

the use of a source of compressed gas (14) for aerosolizing powder medicament in a reservoir. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the inhaler of Calvert et al. to include use of a source of compressed gas as taught by Hansen in order to allow the medicament to be delivered for local therapy (i.e., vagina, ear, wound) or to supplement individuals with a weakened respiratory system (i.e., asthma patients or children that might not be able to inhale strongly enough to properly aerosolize the powder).

As to claims 8, 17, and 32, Calvert et al. is silent as to the particle diameters. Hansen discloses particle size range to predominate (90%) below 5 microns (column 3, lines 45-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used particles sizes that are predominately 1-5 microns as taught by Hansen in the modified Calvert et al. device for delivering the medicament to targeted regions of the lungs.

Claims 21, 24, 35-37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Abplanalp (US 4,396,152).

As to claims 21, 24, and 35, Calvert et al. does not disclose one air inlet not being oriented tangentially in the chamber. However, Abplanalp discloses an aerosolizing device in which one air inlet is not oriented tangentially and a second inlet is not oriented tangentially to create a vortical flow for aerosolizing particles (column 3, lines 38-45). It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have oriented one inlet non-tangentially and one inlet tangentially to the chamber as

taught by Abplanalp in the modified Calvert et al. device for producing the vortical flow. In addition, it appears as though the device disclosed by Calvert et al. would perform equally well with the air inlets oriented in this fashion.

As to claims 36, 37, and 39, please see above rejections with respect to claims 2, 3, 5, 11, 12, and 14.

Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. as applied to claims 2, 5-7, 9-11, 14-26, 18-20, 23, 26, 27, 30, 31, 33, and 34 above, and further in view of Kirk et al. (US 4,860,740). Calvert et al. does not disclose the mouthpiece being oriented tangentially in the chamber. However, Kirk et al., in a powder inhalation device, disclose a mouthpiece oriented tangentially to a chamber containing aerosolized medicament (Figure 1). Therefore, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have oriented the mouthpiece of the modified Calvert et al. device tangentially to the chamber as taught by Kirk et al. for helping produce the vortical flow or for easier exit of the aerosolized medicament from the chamber. In addition, it appears as though the device disclosed by Calvert et al. would perform equally well with the mouthpiece oriented in this fashion.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Calvert et al. in view of Saifer et al. and Abplanalp as applied to claims 21, 24, 35-37, and 39 above, and further in view of Hansen. Calvert et al. as modified by Saifer et al. and Abplanalp does not disclose a source of compressed gas for aerosolizing the medicament. However, Hansen, in a powdered medicament inhaler, discloses the use of a source of compressed gas (14) for aerosolizing powder medicament in a reservoir. It would have been obvious to one of ordinary

skill in the art at the time the invention was made to have further modified the inhaler of Calvert et al. to include use of a source of compressed gas as taught by Hansen in order to allow the medicament to be delivered for local therapy (i.e., vagina, ear, wound) or to supplement individuals with a weakened respiratory system (i.e., asthma patients or children that might not be able to inhale strongly enough to properly aerosolize the powder).

(10) Response to Argument

The rejections based on Calvert et al. and Saifer et al.

Claim 2 and its depending claims

In response to appellant's argument that neither reference discusses the amount of suspension, particularly 40% suspension for delivery through the mouthpiece, examiner respectfully maintains that the structure of Calvert et al. is the same as the instant invention and therefore would be fully capable of delivering the claimed suspension amount. Depending on factors such as the characteristics of the powder being delivered, the size and shape of the chamber, and the patient's presented condition and desired therapy, one of ordinary skill in the art would find it obvious to deliver the claimed suspension by varying the above factors as needed to deliver the desired amount of medicament for treatment. Further, suspension of the claimed amount seems to be a mere optimization of workable ranges by routine experimentation that does not patentably distinguish an invention over the prior art of record. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Examiner further notes that appellant has provided no factual evidence that the prior art is incapable of delivering the claimed amount of suspension, but rather has unsupported statements

in the specification (paragraph 5) and in various remarks that the claimed suspension amount was previously not capable or desirable. It appears as though appellant is claiming secondary consideration arguments from the disclosure on pages 1-4 of the specification. However, examiner notes that the percentages listed in paragraph 5 of the specification refer to the prior art only being able to deliver 8-13% of the medicament to the patient's lung, which does not share any nexus with the claim language of suspending at least 40% by weight of the medicament in the chamber, which has no indication of the amount that is actually delivered to the lung (i.e., it is well known that many powder particles stick to the inside of the inhaler, mouth, and at various locations along the patient's respiratory tract depending on the powder, type of inhaler, etc.). Therefore, these arguments are not convincing.

As pointed out in the above discussion, it is unclear what is structurally different from the prior art and the instant invention that allows the claimed suspension amount because there is nothing in the claims indicating what structure allows the suspension nor evidence showing that the prior art structure was incapable of the claimed suspension amounts. Since the prior art has the same structure as that claimed and a teaching that a maximal amount of medicament delivery is desirable, examiner maintains that optimizing the characteristics of the Calvert et al. device to deliver a suspension of at least 40% of protein powder would have been obvious to one of ordinary skill in the art at the time the invention was made in order to treat an individual patient's condition effectively as needed.

In response to appellant's argument that there is no motivation to combine the references, examiner respectfully maintains that Saifer et al. clearly teaches a powder inhaler formation that utilizes a protein powder in preparation 3. Furthermore, throughout the reference

Saifer et al. discusses a protein powder being inhaled as an aerosol (which can be delivered via any well known means for delivering aerosol including powder inhalers). There is no teaching in Saifer et al. indicating that the powder is incapable of being inhaled by a powder inhaler such as Calvert et al. and therefore examiner respectfully disagrees that that Saifer et al. teaches away from using a powder inhaler.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, it is obvious to deliver a powder medicament with a powder inhaler. The selection of which powder inhaler is an obvious design consideration to one of ordinary skill in the art and selection of Calvert et al.'s inhaler for delivery of the orgotein taught by Saifer et al. would have been obvious because it provides a well known means of effectively delivering powder medicament from an inhaler to a patient. Again, there is no teaching in either reference that the combination would not work.

In response to appellant's argument that there was no problem for which the combination would have been used to solve, examiner maintains that as discussed in the rejections, Saifer et al. discloses a powder medicament for treating the toxic effects of smoke inhalation and Calvert et al. discloses a means for delivering powder medicament to a patient. Therefore, the combination would have been obvious to one of ordinary skill in the art at the time of the

invention because it provides a well known means for delivering powder medicament to a patient and in particular for treating the toxic effects of smoke inhalation.

Claim 11 and its depending claims

In response to appellant's argument that neither reference discusses the volume of aerosolized medicament, particularly 9.24-21.5% of the volume of the chamber, examiner respectfully maintains that the structure of Calvert et al. is the same as the instant invention and therefore would be fully capable of delivering the claimed volume of medicament. Depending on factors such as the characteristics of the powder being delivered, the size and shape of the chamber, and the patient's presented condition and desired therapy, one of ordinary skill in the art would find it obvious to deliver the claimed volume by varying the above factors as needed to deliver the desired amount of medicament for treatment. Further, delivery of the claimed amount seems to be a mere optimization of workable ranges by routine experimentation that does not patentably distinguish an invention over the prior art of record. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Examiner further notes that appellant has provided no factual evidence that the prior art is incapable of delivering the claimed medicament volume, but rather has unsupported statements in the specification (paragraph 5) and in various remarks that the claimed volume was previously not capable or desirable. It appears as though appellant is claiming secondary consideration arguments from the disclosure on pages 1-4 of the specification. However, examiner notes that the percentages listed in paragraph 5 of the specification refer to the prior art only being able to deliver 8-13% of the medicament to the patient's lung, which does not share any nexus with the claim language of a volume of aerosolization that is from 9.24-21.5% of the volume of the

chamber, which has no indication of the amount that is actually delivered to the lung (i.e., it is well known that many powder particles stick to the inside of the inhaler, mouth, and at various locations along the patient's respiratory tract depending on the powder, type of inhaler, etc.). Therefore, these arguments are not convincing.

As pointed out in the above discussion, it is unclear what is structurally different from the prior art and the instant invention that allows the claimed suspension amount because there is nothing in the claims indicating what structure allows the aerosolized volume nor evidence showing that the prior art structure was incapable of providing the claimed volume. Since the prior art has the same structure as that claimed and a teaching that a maximal amount of medicament delivery is desirable, examiner maintains that optimizing the characteristics of the Calvert et al. device to deliver a volume of 9.24-21.5% of the volume of the chamber of aerosolized protein powder would have been obvious to one of ordinary skill in the art at the time the invention was made in order to treat an individual patient's condition effectively as needed.

In response to appellant's argument that there is no motivation to combine the references, examiner respectfully maintains that Saifer et al. clearly teaches a powder inhaler formation that utilizes a protein powder in preparation 3. Furthermore, throughout the reference Saifer et al. discusses a protein powder being inhaled as an aerosol (which can be delivered via any well known means for delivering aerosol including powder inhalers). There is no teaching in Saifer et al. indicating that the powder is incapable of being inhaled by a powder inhaler such as Calvert et al. and therefore examiner respectfully disagrees that that Saifer et al. teaches away from using a powder inhaler.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, it is obvious to deliver a powder medicament with a powder inhaler. The selection of which powder inhaler is an obvious design consideration to one of ordinary skill in the art and selection of Calvert et al.'s inhaler for delivery of the orgotein taught by Saifer et al. would have been obvious because it provides a well known means of effectively delivering powder medicament from an inhaler to a patient. Again, there is no teaching in either reference that the combination would not work as claimed.

In response to appellant's argument that there was no problem for which the combination would have been used to solve, examiner maintains that as discussed in the rejections, Saifer et al. discloses a powder medicament for treating the toxic effects of smoke inhalation and Calvert et al. discloses a means for delivering powder medicament to a patient. Therefore, the combination would have been obvious to one of ordinary skill in the art at the time of the invention because it provides a well known means for delivering powder medicament to a patient and in particular for treating the toxic effects of smoke inhalation.

Claim 26 and its depending claims

Appellant presents no new arguments from those discussed for Calvert et al. and Saifer et al. regarding claim 2. Please see the above response regarding independent claim 2.

The rejections based on Calvert et al., Saifer et al., and Moren et al.

Appellant presents no new arguments from those discussed for Calvert et al. and Saifer et al. Please see the above response regarding independent claims 2, 11, and 26.

The rejections based on Calvert et al., Saifer et al., and Hansen

Appellant presents no new arguments from those discussed for Calvert et al. and Saifer et al. Please see the above response regarding independent claims 2, 11, and 26.

The rejections based on Calvert et al., Saifer et al., and Abplanalp

Appellant presents no new arguments from those discussed for Calvert et al. and Saifer et al. (including for independent claim 35 and its depending claims). Please see the above response regarding independent claims 2, 11, and 26.

The rejections based on Calvert et al., Saifer et al., and Kirk et al.

Appellant presents no new arguments over those discussed for Calvert et al. and Saifer et al. Please see the above response regarding independent claims 2, 11, and 26.

The rejections based on Calvert et al., Saifer et al., Abplanalp and Hansen

Appellant presents no new arguments over those discussed for Calvert et al. and Saifer et al. Please see the above response regarding independent claims 2, 11, 26, and 35.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Kristen C. Matter/

Examiner, Art Unit 3771

Conferees:

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Janet C. Baxter/
TC 3700 TQAS